Decision Memo for Electrostimulation for Wounds (CAG-00068N)

Decision Summary

Electrical stimulation is defined as the application of electrical current through electrodes applied directly to the skin in close proximity to the ulcer. Based on all of the evidence that we have reviewed in this matter, it is our intention to issue a positive coverage decision only on the use of electrical stimulation for chronic Stage III and Stage IV pressure ulcers, arterial ulcers, diabetic ulcers and venous stasis ulcers. All other uses of electrical stimulation for the treatment of wounds are noncovered. Chronic ulcers are defined as ulcers that have not healed within 30 days of occurrence.

Electrical stimulation for the treatment of wounds will not be covered as an initial treatment modality. The use of electrical stimulation will be covered as adjunctive therapy only after there are no measurable signs of healing for at least 30-days of treatment with standard wound therapy and must be used in addition to standard wound care. Measurable signs of improved healing include a decrease in wound size either in surface area or volume, decrease in amount of exudates and decrease in amount of necrotic tissue. Standard wound care includes: optimization of nutritional status; debridement by any means to remove devitalized tissue; maintenance of a clean, moist bed of granulation tissue with appropriate moist dressings; and necessary treatment to resolve any infection that may be present. Specific wound care based on type of wound includes: frequent repositioning of a patient with pressure ulcers (usually every 2 hours); off-loading of pressure and good glucose control for diabetic ulcers; establishment of adequate circulation for arterial ulcers and the use of a compression system for patients with venous ulcers. Wounds must be evaluated at least every 30 days during administration of electrical stimulation therapy. Continued treatment with electrical stimulation is not covered if measurable signs of healing have not been demonstrated within any 30-day period of treatment.

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Decision Memo

TO: File: Electrical Stimulation for the Treatment of Chronic Wounds
CAG -00032

FROM:

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RE: Coverage Decision Memorandum for Electrical Stimulation for the Treatment of Chronic Wounds

DATE: July 23, 2002

This memo serves four purposes: (1) outlines the description and treatment of chronic wounds; (2) reviews the history of Medicare's coverage policies on electrical stimulation for chronic wound treatment, and presents a timeline of recent activities; (3) presents and analyzes the relevant clinical and scientific data relating to the use of electrical stimulation; and (4) delineates the rationale for a positive coverage policy for the use of electrical stimulation for the treatment of certain wound types.

Clinical Background

The normal wound healing process involves inflammatory, proliferative, and remodeling phases. When the healing process fails to progress properly and the wound persists for longer than one month, it may be described as a chronic wound. The types of chronic wounds most frequently addressed in studies of electrical stimulation for wound healing are: (1) pressure ulcers; (2) venous ulcers; (3) arterial ulcers; and (4) diabetic ulcers.

Pressure ulcers, also known, as decubitus ulcers, bedsores or pressure sores, are areas of localized skin/tissue damage caused by unrelieved pressure. This pressure squeezes the skins blood vessels causing hypoxia. If the pressure is prolonged it results in tissue necrosis. Pressure ulcers are most common over bony prominences, such as the sacrum, heels, hips and elbows. Pressure ulcers are generally classified by stage. (See Table 1) Stage I pressure ulcers present as non-blanching erythema with intact skin. Stage II ulcers involve a partial thickness loss involving the epidermis or dermis. Stage III ulcers are full thickness and extend down to, but not through, the underlying fascia. Stage IV ulcers involve tissue below the fascia, exposing muscle and even bone.

Table 1: Staging of pressure ulcers

Stage I	Observable pressure related alteration of intact skin whose indicators as compared to the adjacent or opposite area of the body may include changes in one or more of the following: skin temperature (warmth or coolness), tissue consistency (firm or boggy feel) and/or sensation (pain, itching). The ulcer appears as a defined area of persistent redness in lightly pigmented skin, whereas in darker skin tones, the ulcer may appear with persistent red, blue or purple hues.
Stage II	Partial thickness skin loss involving epidermis, dermis or both. The ulcer is superficial and presents clinically as an abrasion, blister or shallow crater.
Stage III	Full thickness skin loss involving damage to, or necrosis of, subcutaneous tissue that may extend down to, but not through, underlying fascia. The ulcer presents clinically as a deep crater with or without undermining of adjacent tissue.
Stage IV	Full thickness skin loss with extensive destruction, tissue necrosis or damage to muscle, bone, or supporting structures (e.g. tendon, joint capsule). Undermining and sinus tracts also may be associated with Stage IV pressure ulcers.

Prevention of pressure ulcers involves frequent repositioning of the patient, keeping the skin dry and, in some cases, using various support surfaces that keep a person's weight evenly distributed. Once these wounds develop standard wound care includes frequent turning to relieve pressure, proper nutrition and good hygiene are standard therapies. The underlying immobility and difficulty relieving surface pressure points often makes treating these wounds a challenge.

Venous ulcers usually occur in the lower extremities. They result from venous obstruction or valvular incompetence. The subsequent venous hypertension then affects the vascular supply to surrounding tissue, resulting in tissue hypoxia and ulcer formation. Because the underlying pathophysiology is venous insufficiency, the treatment of venous ulcers should ultimately be directed on two fronts - correction of the underlying venous incompetence and wound care. Moist dressings combined with compressive stockings are usually effective in treating these ulcers, although the time to heal may be prolonged in some patients.

Diabetic ulcers are thought to develop from a combination of both small and large vessel disease, which affects tissue perfusion, and peripheral neuropathy, which leads to a loss of protective sensation. Injuries in these patients are often slow to heal, and might go unnoticed. Foot ulcers are a major health problem for diabetics. It is estimated that up to 15% of diabetics will develop a foot ulcer at some time in their life, and approximately 70% of such patients develop recurrent ulcers.[1] Diabetic foot ulcers precede approximately 85% of lower limb amputations.[2] Educating diabetics about routine foot care and self-examination can help to prevent foot ulcers. Moist dressings, debridement and off-loading are the mainstays of treatment.

Arterial ulcers result from inadequate blood flow to the site of a lesion to which blood flow is compromised. The ulcer may be very deep and usually appears black, necrotic, and has no granulation tissue. The surrounding tissue typically shows signs of arterial insufficiency, such as loss of nail growth or atrophic skin. These ulcers usually form between the toes, or on the ankle where the bone protrudes, or on the back of the foot. These ulcers may be very painful and are usually associated with diseases such as arteriosclerosis, systemic lupus erythematosus, or thromboangiitis obliterans. Treatment of the vascular impairment is an important component of good wound care.

Conventional or standard therapy for chronic wounds involves local wound care as well as systemic measures. Standard care considerations to promote wound healing include, debridement or removal of necrotic tissue, wound cleansing, and dressings that promote a moist wound environment. Systemic treatments include the use of antibiotics to control infection and optimizing nutritional supplementation. There are other conventional therapeutic modalities that may apply to certain subgroups of patients depending on their type of wound. Specific conventional therapies for venous ulcers include the use of compression devices aimed at decreasing venous stasis. Patients that have pressure ulcers require frequent repositioning to redistribute the pressure that is causing the ulcers. Off-loading of pressure and good glucose control for diabetic foot ulcers and establish adequate circulation for arterial ulcers. Some clinicians have attempted to supplement conventional wound care therapies with courses of local electrical stimulation. The clinicians that administer electrical stimulation are predominantly physical therapists.

Not long after the discovery of electricity, clinicians tried to derive healing benefits from the application of electrical energy to the human body. Since the 1950's, investigators have used electrical stimulation as a treatment modality for the healing of chronic wounds. The physiologic principles underlying this approach include the hypotheses that electrical stimulation can: (1) increase ATP concentrations in tissues; (2) increase DNA synthesis; (3) attract epithelial cells and fibroblasts to wound sites; (4) accelerate the recovery of damaged neural tissue; (5) reduce edema; (6) increase blood flow; and (7) inhibit pathogenesis.

Electrical stimulation refers to the application of electrical current through electrodes placed directly on the skin in close proximity to the wound. The types of electrical stimulation and devices can be categorized into 4 groups based on the type of current: low intensity direct current (LIDC), high voltage pulsed current (HVPC), alternating current (AC) and transcutaneous electrical nerve stimulation (TENS).[3] Electromagnetic therapy is a related but distinct form of treatment that involves the application of electromagnetic fields rather than direct electrical current.

Food and Drug Administration (FDA) Approval/Clearance

FDA has granted premarket approvals for electrical stimulators as Class III devices for the indications of bone stimulation and deep brain stimulation. FDA has also cleared electrical stimulators as Class II devices when indicated for muscle stimulation. The FDA has not cleared or approved the use of electrical stimulation for the treatment of wounds. The FDA has concluded that the use of these devices for the treatment of wounds is significantly different than the use of these devices for the indications currently covered under a 510(k) clearance. They are considered Class III devices which require the manufacturer to go through the Premarket Approval (PMA) process.[4] Therefore, the manufacturers would have to show there is reasonable assurance of safety and effectiveness for the treatment of wounds before the FDA could issue an approval for these devices. As of this time, the law prohibits manufacturers to market the use of electrical stimulators for wound healing. Lack of approval for this particular indication, however, does not preclude physicians and other health care providers from providing this therapy, as an off-label use.[5]

History of Medicare Coverage

Medicare coverage for electrical stimulation for wound healing has been historically left to carrier discretion. In 1981, however, CMS issued a national noncoverage determination, which barred coverage of a certain type of electrical stimulation (low intensity direct current, Medicare Medicaid Guide Sep. 20, 1981) for the treatment of pressure sores. Carriers had the discretion to cover other forms of electrical stimulation. In August 1995, CMS ordered a technology assessment of electrical stimulation for wound healing. Emergency Care Research Institute (ECRI), a technology assessment firm, was awarded the contract. This report was completed in February 1996.

CMS sent the ECRI report as well as information provided by the American Physical Therapy Association (APTA) to its technology advisory committee (TAC) in November 1996. The TAC, a committee of physicians employed by the government and CMS Contractor Medical Directors, assessed the quality of the clinical studies, and determined that electrical stimulation was not markedly superior or inferior to conventional or alternative therapies for chronic wound healing.

According to the TAC analysis:

“Wound healing is a complex process dependent on, and affected by factors such as volume, location, contamination, foreign bodies, infection, blood supply, edema, drainage, pressure, immobility, repeated trauma, drugs, irritants, topical applications, radiation, age, nutritional status, and co-existing diseases or conditions. Common therapeutic interventions include debridement, irrigation, soaks, topical agents, enzymes, dressings, pressure relief, and antibiotics. Electrical Stimulation (ES) is not commonly included in the standard line of defense for wound healing. The University Hospital Consortium (UHC) considers it an unproven adjunctive therapy for wound healing.”

Similar to the ECRI report, the TAC made the following separate conclusions based on the type of ES being use:

- There is no evidence that Direct Current (DC) improved wound healing.
- Studies did show that Pulsed Current (PC) improves healing rate of stage II-IV pressure ulcers. However, several confounding factors, number of patients, heterogeneity of patients, and no control over concomitant therapy compromised the studies used to reach this conclusion.
- A study did show that Alternating Current (AC) improved the healing rate of pressure ulcers. However, that study had a major flaw, in that the AC group consisted of primarily patients with Stage II ulcers, while the control group consisted of sicker patients with Stage IV ulcers.
- Improvement rate of Pulsed ElectroMagnetic Induction (PEMI) was so small that it was not considered clinically useful.
- Pulsed ElectroMagnetic Energy (PEE) did show improvement in the healing rate for Stage II ulcers when compared to conventional therapy. However, there was no standard of care provided in this study. Both the active and placebo group had 6 different types of dressing and topical agents.

Based on the TAC’s recommendation, in April 1997, CMS rescinded carrier discretion and issued a national noncoverage policy - CIM 35-98 – to be effective May 14, 1997. CMS essentially expanded upon the 1981 national noncoverage decision involving low intensity direct current for the treatment of pressure ulcers by noncovering all forms of electrical stimulation for the treatment of all types of chronic wounds.

In response to this decision, APTA requested a postponement of the effective date and presented additional data. This data was presented on June 17, 1997. After careful review, CMS notified APTA on July 7, 1997 that it planned to proceed with implementation of its noncoverage determination.

Aitken v Shalala

Six individual Medicare beneficiaries joined by the APTA brought suit in federal district court in Massachusetts to challenge CMS's national noncoverage determination [Aitken v. Shalala, 986 F. Supp 57 (D. Mass., 1997)]. The individual plaintiffs suffered from chronic wounds that had not healed with conventional therapies. Some of the plaintiffs alleged that each had experienced facilitated healing when they received adjunctive therapy using electrical stimulation, while other plaintiffs asserted that CMS's decision prevented them from obtaining this adjunctive therapy, which might have helped their wounds to heal. The plaintiffs charged that the administrative record did not adequately support the national noncoverage decision.

The court found that "there needs to be at least a better explanation by HCFA of its coverage determination, and, perhaps, a revision of that determination." 986 F. Supp at 62. The court noted that the administrative record contained a number of published papers concerning the value of electrical stimulation (ES), anecdotal support for the use of ES in clinical settings, publications by the Agency for Health Care Policy and Research (AHCPR), and a report from a health technology assessment consultant –ECRI.[6]

On the ECRI report, the court expressed concern that materials used in a staff presentation to a Technology Assessment Committee had not accurately portrayed some of ECRI's findings. Specifically, the court noted that "ECRI's conclusion that ES is about as effective as other therapies ('not markedly superior or inferior') does not support the conclusion that ES is not effective." Id., at 63. Moreover, the court noted that the record contained anecdotal support from clinicians, and while the agency was not bound to accept this evidence, it was not "free to disregard it entirely, without explanation." Id. In addition, the court specifically noted that AHCPR had issued a clinical practice guideline recommending electrical stimulation for certain ulcers that had proved unresponsive to conventional therapy. Id. at 64. The court noted that the "published studies tend to support the conclusion that ES is about as effective as 'conventional therapy.'" Id. at 64. Finally, the court found that the record lacked adequate information to support the ES national noncoverage determination and questioned whether the record "supports the agency's conclusion that ES should never be covered in any case." Id. The court remanded the national coverage determination regarding reimbursement for ES to the Secretary for additional proceedings to "supplement the record with evidence adequate to support or modify its decision." Id, at 65. Since the court decision, the Medicare carriers have made decisions about Medicare coverage for electrical stimulation of chronic wounds at a carrier-by-carrier level.

After the court's decision, CMS reassessed its coverage policy on electrical stimulation of chronic wounds. Instead of attempting to buttress the administrative record with more documents to support the remanded noncoverage policy, we performed a new, thorough, and extensive analysis. The following actions were the major steps in this coverage determination process:

- On October 14, 1998 CMS received a memorandum from AHRQ's Center for Practice and Technology Assessment. This memo noted that the overall conclusion of the initial ECRI report that "electrical stimulation is about as effective as other therapies ('not markedly superior or inferior')" appear to be accurate. Moreover, it suggested a tempered interpretation of the AHRQ Guidelines on Treatment of Pressure Ulcers. The guidelines state that "electrical stimulation could be considered as treatment for certain pressure ulcers unresponsive to conventional therapy." The recommendation to consider electrical stimulation treatment was made on the basis of level B evidence derived from five clinical trials involving 147 patients (not all receiving the treatment). "These studies were not adequately powered or persuasive because of other methodological faults."
- In an April 1, 1999 letter, APTA responded to the AHRQ letter. In this letter, APTA asked CMS to consider the broad national coverage policy the Association proposed in June 1997. The APTA had proposed a national coverage policy for pulsed current and pulsed electromagnetic induction for the following types of wounds shown non-responsive to conventional therapy: (1) Stage II - IV pressure ulcers, (2) partial and full thickness wounds secondary to venous insufficiency, arterial insufficiency, or diabetic neuropathy.

- CMS performed its own systematic review of the literature to find articles published on this topic since the ECRI report. In addition, we reviewed several articles submitted by APTA for consideration. Given inconsistencies in the quality of the scientific literature and the results reported relating to the effectiveness of electrical stimulation, this issue was referred to the Medical and Surgical Procedures Panel of the Medicare Coverage Advisory Committee (MCAC).

Benefit Category

For an item or service to be covered by the Medicare program it must meet one of the statutorily defined benefit categories outlined in the Social Security Act. Electrical stimulation is covered under the following statutorily defined benefit categories:

§1861(s)(1) Physician's Services

§1861(s)(2)(A) Services and supplies furnished incident to a physician's professional service;

§1861(p) Outpatient Physical Therapy Services

Electrical stimulation is considered a physician or physical therapy service under the Medicare program, and must be performed by a licensed health care professional.

Summary of Evidence

The number of published articles on electrical stimulation for the treatment of chronic wounds has increased considerably since the early 1990's. There have also been hundreds of articles published on wound care in general. Of these, several are review articles and clinical practice guidelines. One of the most extensive, initial reports was produced by the Agency for Health Care Policy and Research (AHCPR), now known as the Agency for Healthcare Research and Quality (AHRQ) in 1994. Although this report focused largely on pressure ulcers, it advised clinicians to "consider a course of electrotherapy for Stage III and IV pressures ulcers that have proved unresponsive to conventional therapy."[7] This recommendation was based on "data from five clinical trials, involving a total of 147 patients" and was given a "B" rating for strength of evidence.[8]

In 1996, CMS (then the Health Care Financing Administration) commissioned ECRI to conduct a technology assessment on electrical stimulation for the treatment of chronic wounds. ECRI searched 17 databases (some starting from 1969 to January, 1996) and identified 41 studies (18 randomized controlled trials, 22 case series and case reports, 1 comparative study) of electrical stimulation for the treatment of chronic wounds. ECRI's definition of a chronic wound was a duration of 30 days or longer. They conducted several extensive analyses including a qualitative analysis of all studies, a quantitative analysis of normalized healing rates, a meta-analysis of normalized healing rates and a meta-analysis of proportion of lesions completely healed.

ECRI made the following qualitative conclusions: (1) "Although all ES (electrical stimulation) studies have at least 1 weakness, not all are potentially confounded." (2) "ES controlled studies for venous ulcers are about equal to or slightly inferior in quality compared to other controlled studies for venous ulcers." (3) "ES controlled studies for decubitus ulcers are about equal to or slightly superior in quality compared to other controlled studies for decubitus ulcers." ECRI made the following quantitative conclusions: (1) "ES facilitates the healing rate of chronic ulcers." (2) "ES facilitates the complete healing of chronic ulcers." (3) "The relationship between outcomes and ES can be affected by wound size and type of stimulator." (4) "Decubitus ulcers are more likely to heal completely in response to ES than venous ulcers." ECRI's general findings were: (1) "ES devices are safe when used appropriately." (2) Most types of ES are more effective than minimal treatment (e.g., saline-soaked gauze)." (3) "ES is not markedly superior to or inferior to conventional or alternative therapies. There is insufficient evidence to determine if clinically significant differences exist." Conventional therapies were defined as "debridement, cleaning agents, topical agents, dressings, bandages, antibiotics (systemic or local), compression therapies, systemic medications, or nutritional supplements." Alternative therapies were defined as "hyperbaric oxygen, growth factors, ultrasound, lasers, and ultraviolet light."[9]

Although ECRI considered electrical stimulation and electromagnetic therapy collectively, these two treatment modalities are distinct in application and mechanism of action. For the remainder of this discussion, electrical stimulation and electromagnetic therapy will be considered separately. Electrical stimulation of chronic wounds is defined as the application of electrical current through electrodes placed directly on the skin in close proximity to a wound. Electromagnetic therapy of chronic wounds refers to treatment with electromagnetic fields.

Evidence on Electrical Stimulation for the Treatment of Chronic Wounds

Since the ECRI technology assessment was published in 1996, CMS performed an additional search of the literature to identify more current evidence on the effectiveness of electrical stimulation for the treatment of chronic pressure, venous, arterial and diabetic wounds. Medline from 1996 to April 2002 was searched iteratively using the following key words: electrical stimulation, electric stimulation or electrotherapy with wound(s) or ulcer(s). Searches were limited to human subjects and English language publications. Only studies that were not included in the ECRI technology assessment and assessed wound healing were reviewed. Four additional articles and a recent technology assessment were found and are summarized below.

In 1996, Baker and colleagues randomly assigned 80 patients (82.5%, age range of 17-76 years) with spinal cord injuries to one of three stimulation groups: group A received asymmetric, biphasic stimulation; group B received symmetric, biphasic stimulation; and group MC received microcurrent stimulation. The control group received the same stimulation procedures but no electrical current was applied. Patients were treated until their ulcers healed, the physician intervened, or the patient withdrew. Electrical stimulation was administered through surface, carbon-rubber electrodes. The number and size of electrodes varied, depending on the size and location of the ulcer. A total of 192 surgical and pressure ulcers were treated. The authors stated that “no statistical differences were found in initial or discharge ulcer areas or in the mean healing rates among the four treatment groups.” When wounds were divided into “good responses” (healed during stimulation) or “poor responses” (non healing ulcers), the authors stated that “statistical analysis of only the good response group showed a significant difference between the A protocol and the MC and C (control) protocols.” They also noted “no significant differences were found between the B protocol and the other treatments.”[10] One-way analysis of variance was used in the analysis of healing rates.[11] Twenty-seven (14%) of the 192 wounds “withdrew.” Sixty-three (33%) of wounds had a “change of program.” The number of patients that withdrew from the study was not reported. Intention-to-treat analysis was not used. The results of multivariate analyses to adjust for confounding variables were not presented.

In 1997, Baker and colleagues randomly assigned 80 patients (69% male, age range of 30-82 years) with spinal cord injuries to one of three stimulation groups: group A received asymmetric, biphasic stimulation; group B received symmetric, biphasic stimulation; and group MC received microcurrent stimulation. The control group received the same stimulation procedures but no electrical current was applied. Patients were treated until their ulcers healed, the physician intervened, or the patient withdrew. Electrical stimulation was administered through surface, carbon-rubber electrodes. Three treatment sessions of 30-minute duration were provided daily. A total of 114 wounds were treated. The authors stated that the mean healing rates among the four groups were not significantly different. After combining the MC group with the control group (total of 39 wounds), the authors reported, “the combined control group was statistically slower to heal than the treatment group A.”[12] One-way analysis of variance was used in the analysis of healing rates. Statistical significant was set at a p-value <0.05. Twenty-eight (25%) of the 114 wounds “withdrew.” Twenty-four (21%) of wounds had a “change of program.” The number of patients that withdrew from the study was not reported. Intention-to-treat analysis was not used. The results of multivariate analyses to adjust for confounding variables were not presented.

In a 1999 single arm pre-post study of patients with poor response to conventional therapy, Sumano and colleagues reported that 93% of patients experienced greater than 90% recovery of wounds following acupuncture-like electrical stimulation. The investigators studied 44 patients (age range of 15-60 years) with various skin wounds including venous ulcers, diabetic ulcers, surgical wounds and burns that had received conventional treatment with unsatisfactory results. Electrical stimulation was applied via electrodes clipped to stainless steel acupuncture filiform needles for 20 minutes. Treatment was applied daily or every other day depending on wound severity until no further progress could be observed (mean treatment = 24.5 days for the most severe wounds). The authors reported that 41 patients (93%) experienced excellent outcomes (>90% recovery); 3 patients (7%) had fair responses (60-90% recovery); and no patients had poor responses (less than 50% recovery).[13]

In 1999, Gardner and colleagues published the results of a meta-analysis on the effect of electrical stimulation on chronic wound healing. The authors analyzed 15 studies (9 randomized clinical trials (RCTs), 5 nonrandomized trials, 1 descriptive study), which included 24 electrical stimulation samples and 15 control samples. The type of wounds varied among studies as did the type of stimulation used. The mean percentage healing per week (PHW) was determined for each electrical stimulation (ES) and control (C) sample. The mean PHW was 22.22% (95% confidence interval =18.08-26.35%) for ES samples and 9.10% (95% confidence interval =3.82-14.38%) for control samples for all 15 studies. For blinded, placebo -controlled randomized clinical trials only, the mean PHW was 22.51% (95% confidence interval =15.44-29.58%) for ES samples and 9.01% (95% confidence interval =1.09-16.93%) for control samples. The 95% confidence intervals did not overlap when all 15 studies were analyzed. The 95% confidence intervals did overlap when the analysis included only blinded, placebo-controlled RCTs. The authors stated, “although electrical stimulation produces a substantial improvement in the healing of chronic wounds, further research is needed to identify which electrical stimulation devices are most effective and which wounds respond best to this treatment.”[14]

In 2001, Cullum and colleagues published a technology assessment that was commissioned by the National Health Service Research and Development Health Technology Assessment Programme (NHS R&D HTA). The authors searched 19 databases for the period up to December 1999 and reviewed 16 randomized controlled trials, with the last study published in 1997. The authors reported the following: (1) For the treatment of chronic wounds, “the two small trials identified suggest a benefit associated with electrotherapy compared with sham electrotherapy or no electrotherapy to heal chronic wounds.” (2) For the treatment of venous leg ulcers, “no RCTs (randomized controlled trials) of the use of electrotherapy in treating venous leg ulcers were identified.” (3) For the treatment of ischemic ulcers, no recommendations for practice can be made.” (4) For the treatment of diabetic ulcers, “the one trial identified demonstrated no significant difference in ulcer healing between the intervention and control groups.” (4) For the treatment of pressure ulcers, “the three trials identified suggest a benefit associated with using electrotherapy to treat pressure sores.” The authors concluded: “Further research is required to clarify the relationship between the various physical therapies and chronic wound healing. The most promising physical therapies for further investigation are ultrasound for the treatment of venous leg ulcers and electrotherapy for the treatment of pressure sores.”[15]

Evidence on Electromagnetic Therapy for the Treatment of Chronic Wounds

For electromagnetic therapy, ECRI stated the following: (1) “No evidence that PEMF (pulsed electromagnetic field) stimulation improves the healing rate of chronic decubitus or diabetic ulcers.” (2) No evidence that PEE (pulsed electromagnetic energy) stimulation improves the healing rate of chronic venous or diabetic ulcers.” (3) “Insufficient data to determine whether PEE stimulation improves the normalized healing rates for stage III or IV decubitus ulcers.”

To identify additional evidence on the effectiveness of electromagnetic therapy for the treatment of chronic wounds since the ECRI report, CMS performed a separate search of the literature. Medline from 1996 to April 2002 was searched iteratively using the following key words: electromagnetic therapy and electromagnetic with wound(s) or ulcer(s). Searches were limited to human subjects and English language publications. Excluding articles reviewed by ECRI, we did not find any new primary research on the effectiveness of electromagnetic therapy on healing of chronic wounds or ulcers. There were 3 review articles that commented on electromagnetic therapy. They are summarized below.

In 1999, Houghton and Campbell authored a review of adjunctive therapies for the treatment of chronic wounds. They evaluated ultrasound, laser, ultraviolet light, superficial heating, pulsed electromagnetic fields and electrical stimulation; and concluded “electrical stimulation and ultrasound are the only therapeutic modalities that currently have sufficient clinical research evidence to support their use in the treatment of chronic wounds.”[16]

In 2000, Sheffet and colleagues authored a review on electric and electromagnetic energy as adjuvant treatment for pressure ulcers. They reported that only moist wound dressings and adjunctive electrotherapy for unresponsive Stage III and IV pressure ulcers “receive high ratings for reported experimental evidence of validity.”[17]

In 2001, HTA technology assessment reported the following: (1) “Only three small trials with a total of 92 patients were identified. These trials provided no evidence of a benefit of electromagnetic therapy for venous leg ulcers.” (2) Two small trials, with a total of 55 patients, were identified. These provide no clear evidence of a benefit of electromagnetic therapy for the treatment of pressure sores.”[18]

Medicare Coverage Advisory Committee

On October 17th, 2000 the Medical Surgical Procedures Panel of the Medicare Coverage Advisory Committee (MCAC) met to discuss the topic of electrical stimulation for the treatment of wounds. This panel included nationally recognized experts in clinical and academic medicine, health services research, and ethics. In preparation for this meeting the panel was sent the following materials:[19]

- Technology assessment prepared by ECRI in 1996 and the update to the technology assessment prepared by ECRI in 1997
- Literature review prepared by CMS since the ECRI report
- AHCPR Guidelines on Treatment of Pressure Ulcers

- Bibliography and copies of all articles

During the panel meeting, nine speakers from various organizations made presentations, representing a wide range of interests. These speakers included professional societies, such as the APTA, Association for the Advancement of Wound Care, and physicians. Dr. Rita Frantz, an expert on wound care suggested by the APTA, provided an overview of electrical stimulation for the treatment of wounds.

As part of the meeting, the panel was asked to vote on a series of questions:

1. Is the evidence adequate to draw conclusions about the effectiveness of electrical stimulation as an adjunctive therapy for chronic pressure ulcers?

2. Is the evidence adequate to draw conclusions about the effectiveness of electrical stimulation as an adjunctive therapy for chronic venous ulcers?

3. Is the evidence adequate to draw conclusions about the effectiveness of electrical stimulation as an adjunctive therapy for chronic arterial/diabetic ulcers?

In answering these questions, they were asked to consider the following points:

Adequacy of study design – Is there evidence that the studies do not over or underestimate the effect of the intervention? For example, do patients who received the intervention differ systematically from those in the control group in ways that might affect outcomes? Do studies permit conclusions about the health outcome effects of the technology?

Consistency of results – Are the results of the studies consistent or are they contradictory?

Applicability to the Medicare population – Are the results of the studies applicable to the various Medicare populations?

Expert testimony – Public comments, etc. should be considered with respect to the above considerations.

If the evidence is adequate to draw conclusions about the effectiveness of electrical stimulation as an adjunctive therapy, the panel was then asked what is the size of the overall health effect? If the evidence is found to be adequate the panel must then rate the effectiveness of the evidence.

Actions of the Panel

The panel decided to modify the first question to: “Is there adequate evidence to draw conclusions about the effectiveness of electrical stimulation, as an adjunctive therapy for chronic non-healing pressure, venous, and arterial ulcers? The panel decided not to distinguish between the types of wounds. Several panel members believed there was adequate evidence, at least in the aggregate, to draw a conclusion as to the effectiveness of electrical stimulation used for the treatment of chronic, non-healing pressure ulcers. In addition, some members of the panel stated that the evidence is clearly best for pressure sores and that aggregating the data enabled them to vote in the affirmative.

With regards to the second question, the panel concluded that the use of electrical stimulation for the treatment of chronic, non-healing wounds would be considered more effective, which means this intervention “improves health outcomes by a significant, albeit small, margin as compared with established medical items or services.”[20]

Issue of different types of devices

At this meeting, CMS decided to defer to the panel’s discretion whether or not to answer the questions separately for each of the different types of electrical stimulation: direct current, pulsed direct current, alternating current or transcutaneous electrical nerve stimulation or pulsed electromagnetic field stimulation.

Dr. Frantz, PhD was recommended by the APTA to give an overview of the role of electrical stimulation in chronic wound healing. Dr. Frantz is a professor of nursing at the University of Iowa. Over the past 12 – 15 years she has studied the use of electrical stimulation to treat wounds of elderly patients primarily in nursing homes. She has received two NIH funded grants to study the effects of electrical stimulation, specifically TENS, on wound healing.

Dr. Frantz did address the issue of the different types of devices. Dr. Frantz stated that there are primarily four types of devices used to some extent in wound healing. Low intensity direct current, high voltage pulse current and two forms of alternating current – low voltage pulse micro-amperage current and TENS. According to Dr. Frantz, “you do see an occasional reference to the use of electromagnetic fields, it is different than electrical stimulation, which is using current. The research on electromagnetic field has been more limited particularly in humans…studies done do not provide us with much information about what this electromagnetic field might do in a chronic wound.”

The panel decided not to vote on the various types of delivery systems for electrical stimulation. The panel appeared to believe that it could not get into great detail about the differences between the devices. However, the initial request for coverage filed by APTA proposed that CMS cover Pulsed Current (PC) and Pulsed (non-thermal) Electromagnetic Induction (PEMI) for the treatment of wounds. The panel ultimately concluded that they remained uncertain about whether there are differences in the technologies.

On February 21, 2001 the MCAC Executive Committee met and ratified the recommendations of the Medical/Surgical Procedures Panel. On May 1st, 2001 CMS received signed minutes from the February Executive Committee Meeting.

CMS Analysis

National coverage determinations (NCDs) are determinations by the Secretary with respect to whether or not a particular item or service is covered nationally under title XVIII of the Social Security Act. §1869(f)(1)(B). In order to be covered by Medicare, an item or service must fall within one or more benefit categories contained within Part A or Part B, and must not be otherwise excluded from coverage. Moreover, with limited exceptions, the expenses incurred for items or services must be "reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member." § 1862(a)(1)(A).

Our analysis focused on 4 questions:

1. Is there evidence on the effectiveness of electrical stimulation on the healing of chronic wounds, such as chronic pressure, venous, arterial and diabetic wounds?
2. Is there evidence on the most effective type of device and form of electrical stimulation?
3. Is there evidence on the optimal duration of treatment with electrical stimulation?
4. Is there evidence on the effectiveness of electromagnetic therapy on healing of chronic wounds?

Is there evidence on the effectiveness of electrical stimulation on the healing of chronic wounds?

The evidence on the clinical effectiveness of electrical stimulation in the treatment of chronic wounds has grown substantially since the early 1990's. Specifically, the studies have focused almost entirely on several types of chronic wounds: pressure ulcers, diabetic ulcers and ulcers due to venous or arterial insufficiency. Also, in their 1994 clinical practice guideline AHCPR, now known as AHRQ, recommended that electrotherapy be considered for unresponsive Stage III and IV pressure ulcers (strength of evidence level B).

Since the CMS-commissioned ECRI Technology Assessment, several additional studies, including two randomized clinical trials, have reported a benefit in wound healing with electrical stimulation. In addition, the MCAC Medical Surgical Procedures Panel voted in favor of electrical stimulation for the treatment of chronic wounds in 2000. Lastly, the 2001 NHS technology assessment concluded that there was a benefit associated with electrotherapy for chronic wounds. Although, the clinical studies reviewed had important limitations, the large body of evidence as a whole is adequate to conclude that electrical stimulation is clinically effective, and therefore, reasonable and necessary, for the treatment of the following chronic wound types under certain conditions after an adequate trial of standard wound therapy: chronic Stage III and Stage IV pressure ulcers, chronic ulcers due to arterial or venous insufficiency or diabetes mellitus. Chronic ulcers are defined as "open lesions that have not healed within 30 days of their occurrence."[21] Generally, most chronic wounds will heal with good standard wound therapy. Only a small minority of chronic wounds may require additional therapies as an adjunct to standard wound therapy to heal completely.

CMS' decision is based on evidence that pertains to specific ulcer types. Although the MCAC elected not to distinguish the evidence based on wound type, CMS believes that different types of wounds may respond differently to a given treatment because the etiology of ulcers varies. For example, the etiology of a pressure ulcer relates to pressure whereas the etiology of arterial ulcers ulcers is vascular. A therapy that reduces pressure, such as pressure-reducing air mattresses, are clinically effective for some decubiti ulcers but not for arterial ulcers. Therefore, it is difficult to generalize the findings from studies on clinically effective therapies for one type of ulcer to other types. The FDA has taken a similar position. In a draft document "Guidance for Industry – Chronic Cutaneous Ulcer and Burn Wounds – Developing Products for Treatment", the FDA stated: "Wounds differ pathophysiologically, making it difficult – if not impossible – to generalize results obtained from a trial conducted in patients with one type of wound to those with another wound type. Separate safety and efficacy data should be submitted for each wound type for which an indication is sought."[22]

Clinical studies that we have reviewed addressed the use of electrical stimulation therapy when performed by a licensed therapist trained in wound care management. The studies did not adequately evaluate unsupervised home use of the device by a patient.

Is there evidence on the most effective type of device and form of electrical stimulation?

There was insufficient evidence to determine the best type of device and most effective form of electrical stimulation for the treatment of chronic wounds or ulcers. There appears to be no standard type, waveform, or frequency of electrical stimulation. The treatments varied between studies but involved one of 4 basic forms: low intensity direct current (LIDC), high voltage pulsed current (HVPC), alternating current (AC) and transcutaneous electrical nerve stimulation (TENS).[23] Therefore, CMS cannot determine if one type of electrical stimulation is more or less clinically effective than another type.

Is there evidence on the optimal duration of treatment with electrical stimulation?

In general, the duration of treatment differed among studies, often depending on the size of the initial ulcer and rate of healing. In the majority of clinical trials, electrical stimulation was given 3 times per week until the chronic ulcer healed. There was no direct evidence to determine the optimal duration or amount of electrical stimulation. However, it would be clinically rational and appropriate to discontinue treatment with electrical stimulation if the ulcer is not healing.

Consistent with previous CMS coverage decisions (e.g. CIM 60-19 Air-Fluidized Beds decision) and the AHCPR guidelines, a chronic wound should demonstrate progressive healing within 4 weeks if the treatment being used is effective. Therefore, if progressive healing is not demonstrated after a 30-day period of treatment, electrical stimulation is unlikely to provide benefit. Progressive healing is generally demonstrated by decrease in wound size in surface area or volume, decrease in amount of exudates, and decrease in amount of necrotic tissue.

Is there evidence on the effectiveness of electromagnetic therapy on healing of chronic wounds?

Unlike the situation with electrical stimulation, we did not identify any new studies on the effectiveness of electromagnetic therapy since the ECRI technology assessment. In 1996, ECRI reported that there was no evidence or insufficient data on the clinical effectiveness of electromagnetic therapy.[24] Since then, two published reviews (Houghton and Campbell,[25] Sheffet and colleagues[26]) and the HTA technology assessment[27] have reiterated and reinforced this position. There appears to be at least an informal consensus since all reports had similar conclusions. The paucity of new research and evidence also raises questions about the clinical utility of electromagnetic therapy for the treatment of chronic wounds. Based on these reports, the evidence is adequate to conclude that electromagnetic therapy is not clinically effective, and therefore, not reasonable and necessary, for the treatment of chronic wounds. Thus, Medicare will not cover any form of electromagnetic therapy for the treatment of chronic wounds. Further primary research is needed to fully evaluate this treatment modality.

DECISION:

Electrical stimulation is defined as the application of electrical current through electrodes applied directly to the skin in close proximity to the ulcer. Based on all of the evidence that we have reviewed in this matter, it is our intention to issue a positive coverage decision only on the use of electrical stimulation for chronic Stage III and Stage IV pressure ulcers, arterial ulcers, diabetic ulcers and venous stasis ulcers. All other uses of electrical stimulation for the treatment of wounds are noncovered. Chronic ulcers are defined as ulcers that have not healed within 30 days of occurrence.

Electrical stimulation for the treatment of wounds will not be covered as an initial treatment modality. The use of electrical stimulation will be covered as adjunctive therapy only after there are no measurable signs of healing for at least 30-days of treatment with standard wound therapy and must be used in addition to standard wound care. Measurable signs of improved healing include a decrease in wound size either in surface area or volume, decrease in amount of exudates and decrease in amount of necrotic tissue. Standard wound care includes: optimization of nutritional status; debridement by any means to remove devitalized tissue; maintenance of a clean, moist bed of granulation tissue with appropriate moist dressings; and necessary treatment to resolve any infection that may be present. Specific wound care based on type of wound includes: frequent repositioning of a patient with pressure ulcers (usually every 2 hours); off-loading of pressure and good glucose control for diabetic ulcers; establishment of adequate circulation for arterial ulcers and the use of a compression system for patients with venous ulcers. Wounds must be evaluated at least every 30 days during administration of electrical stimulation therapy. Continued treatment with electrical stimulation is not covered if measurable signs of healing have not been demonstrated within any 30-day period of treatment.

Medicare will not cover any form of electromagnetic therapy for the treatment of chronic wounds. Electrical stimulation should be discontinued when the wound demonstrates a 100% epithelialzed wound bed. Electrical stimulation for wound healing is not covered in the home setting, as unsupervised use by patients in the home has not been found to be medically reasonable and necessary.

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1 Valk G et al., 2001.

2 Ibid.

3 Gardner et al., 1999.

4 The Medical Device Amendments of 1976 to the Federal Food, Drug, and Cosmetic Act (the act) established three regulatory classes for medical devices. The three classes are based on the degree of control necessary to assure that the various types of devices are safe and effective. The most regulated devices are in Class III. The amendments define a Class III device as one that supports or sustains human life or is of substantial importance in preventing impairment of human health or presents a potential, unreasonable risk of illness or injury . Insufficient information exists on a Class III device so that performance standards (Class II) or general controls (Class I) cannot provide reasonable assurance that the device is safe and effective for its intended use. Under Section 515 of the act, all devices placed into Class III are subject to premarket approval requirements. Premarket approval by FDA is the required process of scientific review to ensure the safety and effectiveness of Class III devices.

Before such devices can be marketed, they must have an approved premarket approval application or be reclassified into Class I (general controls) or Class II (standards).

Class III transitional devices and "new" devices (described in the paragraph above) are automatically classified into Class III by statute and require premarket approval by FDA before they may be commercially distributed.

5 In addition, lack of FDA approval or clearance for a specific non-labeled indication, when there are other labeled indications, is not an automatic disqualification for Medicare coverage.

6 AHCPR is now known as the Agency for Healthcare Research and Quality (AHRQ).

7 *Clinical Practice Guideline:Treatment of Pressure Ulcers,* U.S. Department of Health and Human Services, Public Health Service, Agency for Health Care Policy and Research, December 1994.

8 AHCPR defined “B” strength of evidence as: “Results of two or more controlled clinical trials on pressure ulcers in humans provide support, or when appropriate, results of two or more controlled trials in an animal model provide indirect support.”

9 ECRI, 1996.

10 Baker et al., 1996.

11 Analysis of variance (ANOVA) is a statistical procedure that is often used to compare means between groups. One way ANOVA is the simplest type and allows examination of one factor (usually the treatment intervention), but does not permit consideration of other explanatory independent variables.

12 Baker et al., 1997.

13 Sumano and Mateos, 1999.

14 Gardner et al., 1999.

15 Cullum et al., 2001.

16 Houghton and Campbell, 1999.

17 Sheffet et al., 2000.

18 HTA, 2001.

19 The Health Technology Assessment conducted by the National Health Service was not sent to the panel, since it had not yet been published.

20 Medicare Coverage Advisory Committee Executive Committee, Recommendations for Evaluating Effectiveness, May 20, 2001.

21 ECRI, 1996

22 Guidance for Industry: Chronic Cutaneous Ulcer and Burn Wounds – Developing Products for Treatment. FDA/CBER/CDRH/CDER Draft, June 2000

23 Gardner et al., 1999.

24 ECRI, 1996.

25 Houghton and Campbell, 1999

26 Sheffet et al., 2000.

27 HTA, 2001.

April 1, 1999 - Letter from the American Physical Therapy Association (APTA) concerning the ECRI and AHCPR letter
October 14, 1998 - Letter from Agency for Health Care Policy and Research (AHCPR)
January 23, 1998 - Letter from ECRI concerning Aiken v. Shalala

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